DROP MASTER (A)

Drop Master is a device used for monitoring the rate of fluid administered intravenously. The device was invented and developed at Smith Kline Instruments Inc. After the Drop Master was put on the market, a number of service calls from the customers indicated that the device was too sensitive to temporary flow rate changes. Marty Kienitz made the design improvements to provide the system with the capability of sustaining temporary disparity in the flow from the set rate.

 Prepared for the Stanford Engineering Case Program by Mr. R. Ganeriwal under the direction of Professor Henry O. Fuchs with financial support from the National Science Foundation. The assistance of Mr. Marty Kienitz and Mr. Paul Goldberg is gratefully acknowledged.

DROP MASTER (A)

During an informal meeting, Marty Kienitz and others in the group were asked by their boss, Tom Corbin, whether there was anything that could be done to alleviate complaints received about the alarm system in the Drop Master without losing the accuracy and fail-safe features incorporated in the device.

The Drop Master is a device for accurately monitoring the rate of fluid given intravenously. It was invented by Tom Corbin who is a Vice-President of Smith Kline Instruments Inc. (SKII) in Palo Alto, California. He is in charge of the Research and Development section at SKII. Exhibit A-1 shows the Drop Master and the other components of an intravenous feeding system. Exhibit A-2 shows closer views of the Drop Master.

The Drop Master features an electronic flow control mechanism whereby the desired flow rate can be "dialed in." In addition, the device has an alarm which sounds in the event of improper flow. The Drop Master was received with great enthusiasm by hospitals and medical institutes as a replacement for the simple mechanical clamps for controlling the flow in intravenous fluid dispensing systems.

SKII has been in the business of designing, developing and manufacturing instruments for medical applications since 1956. The company currently employs 200 people including 40 engineers from numerous fields. The company's main facilities are located in Palo Alto, with sales offices all over the United States. All the design and fabrication work is done in Palo Alto.

Marty Kienitz received his B. A. from the University of Minnesota and holds a Master's Degree in Physics from the University of Southern California. He has been with the company for two years. Before he came to SKII, he was employed in the electro-optical section at Sylvania Inc. in Mountain View, California. This is Marty's fourth job since his graduation in 1956. His main reasons for joining SKII were the "non-defense" work and his preference for a smaller company in the bay area.

Marty works in the capacity of a research and development engineer under Tom Corbin. The group of engineers under Tom works very closely. Information about work in progress within the group is relayed at informal meetings. The job assignments are mostly informal. The case of the Drop Master is an example in which Tom mentioned the problem for the engineers to think about. In such informal assignments, the engineer who comes up with the most concrete ideas usually proceeds with the development of the concepts. A team effort may be involved to implement these concepts into an actual device.

Figure 1 shows a schematic diagram of the intravenous fluid dispensing system. The fluid to be fed intravenously is stored in the bottle (a). The fluid from this bottle goes to the drop chamber (b). The function of the drop chamber is to eliminate the influence of varying liquid level in the bottle (a) on the rate of flow of the fluid. In addition, it provides a means of visual examination of the rate at which fluid is being given to the patient. The rate of flow is measured in drops per minute, a common scale for flow measurement in such devices. The flow rate can thus be verified by counting the drops falling in the transparent drop chamber in a measured interval of time. The electronic control system for monitoring the rate of flow and the alarm system are contained in the housing designated as drop master (g). A solenoid operated valve (f) is located at the lower end of the drop master. The valve (f) is designed to be either open or closed, i.e., it is not a proportional valve. In the closed position, the valve depresses the plastic tube (e) to prevent any flow. The rate of flow is varied by the frequency of opening and closing of this valve. A photoelectric drop sensor (c) and a light source (d) are attached to the drop chamber as shown in the figure. An electric pulse is generated each time a drop falls in the drop chamber, between the photoelectric pickup and the light source.

The control system in the Drop Master includes a pulse generator which can be set at a rate between 5 to 150 pulses per minute to serve as rate generator or "clock." The pulse from the rate generator activates the solenoid to open the spring loaded valve (f) momentarily and let an amount of fluid, equivalent to a drop, pass through the system. Lowering of the fluid in the

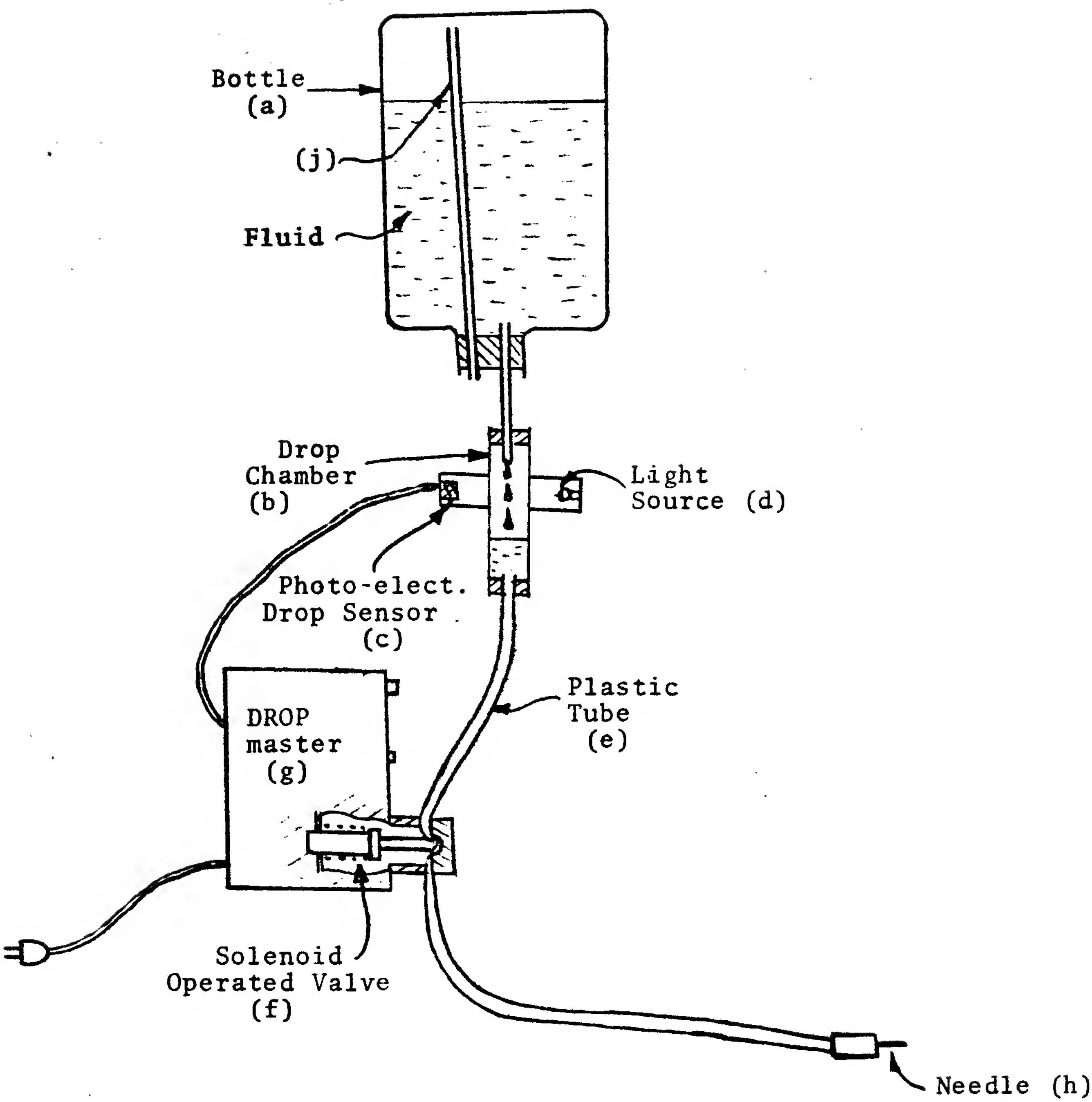


Figure 1. Schematic Diagram - Intravenous Fluid Dispensing System

drop chamber causes a drop to flow from the storage bottle (a) into the drop chamber (b) and this drop is sensed by the photoelectric drop sensor (c).

The electronic control system in the Drop Master is designed so that it must receive alternate pulses from the rate generator and the photoelectric drop sensor. The system goes into the alarm state if two consequent pulses are received from the same source. A copy of the patent, included as Exhibit A-3, describes in detail the logic built into the system whereby there must be one drop pulse for each clock pulse, no more - no less, or the system will go into an alarm state. In such an event, power is disconnected from the solenoid valve so that it closes and a warning buzzer is sounded. The system stays in the alarm state until an attendant operates a reset switch on the front panel of the Drop Master. The actual drop rate is thus very tightly controlled by the rate generator.

The number of service calls from customers became excessive some time after the introduction of the Drop Master on the market. The problem, in general, was that the control system was too sensitive to momentary changes in drop rate. It would alarm whenever there was a temporary increase or decrease of resistance to flow. Under these circumstances, the attendant had to return and reset it before the flow could be resumed, even though there was no failure in any of the components of the system.

Some of the conditions which caused temporary changes in the flow rate (drop signal phase) are given below:

1) The patient may change position, either bending the plastic tubing or causing the opening in the needle end to press against the wall of the vein. This impedes flow, causes the drop signal to fall behind the rate generator which sounds the alarm.

2) A change in the patient's position may also act to reduce the resistance to flow. A sudden reduction in back pressure may allow two drops to form and fall in rapid succession. This will advance the phase of the drop signal ahead of the rate generator, and cause an alarm.

3) The plastic tube (designated by e in Figure 1) is normally pinched shut by the solenoid valve. When a clock pulse calls for another drop, the solenoid immediately pulls open, but the plastic tube does not always open as quickly or as fully. This causes a delay in the drop formation. If the desired drop rate is set high, the tube may not open before another pulse is generated.

4) The Drop Master is sometimes used with an infant's intravenous set, which has smaller tubing and a smaller drop orifice and drop chamber. The drops are smaller and they form quickly; occasionally so quickly that two drops fall before the solenoid valve has time to close. The drop rate signal is then ahead and the system alarms.

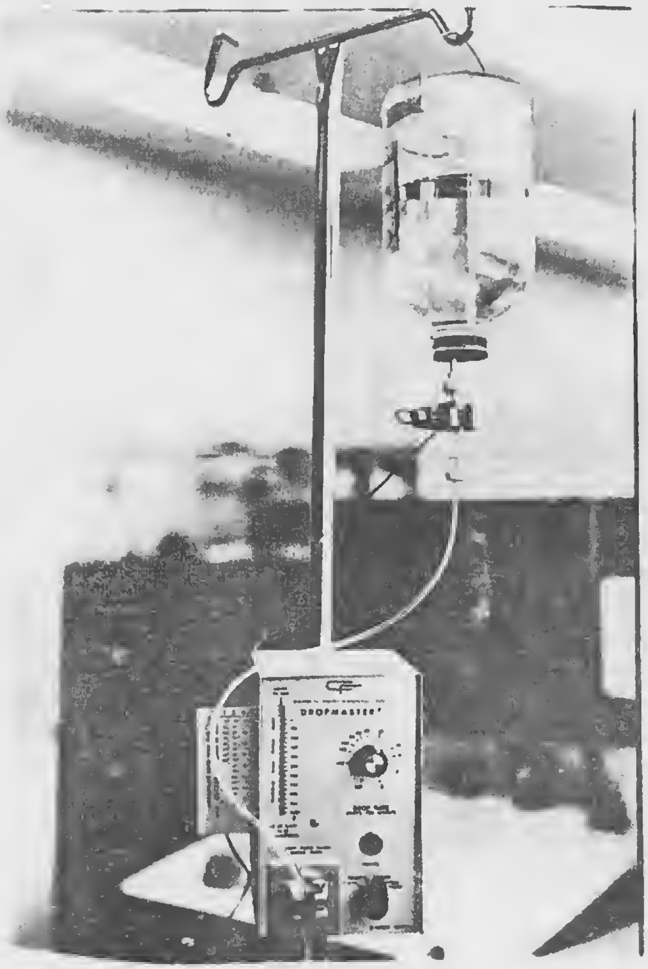
Marty recalls: "It was a very strange situation. We were spending money and time on the service calls and yet the alarm conditions were not due to a defect in our hardware. Actually, if the conditions of improper flow were to exist for a period of time, rather than being temporary, the Drop Master <u>must</u> shut down and sound the alarm for the patient's safety."

The Drop Master was withdrawn from the market.

Besides Tom Corbin, Mr. Fransworth, Vice President in charge of sales and marketing had also asked Marty to look into the possibility of solving this problem so that the Drop Master could be put back on the market.

EXHIBIT A-1

Intravenous Fluid Dispensing System



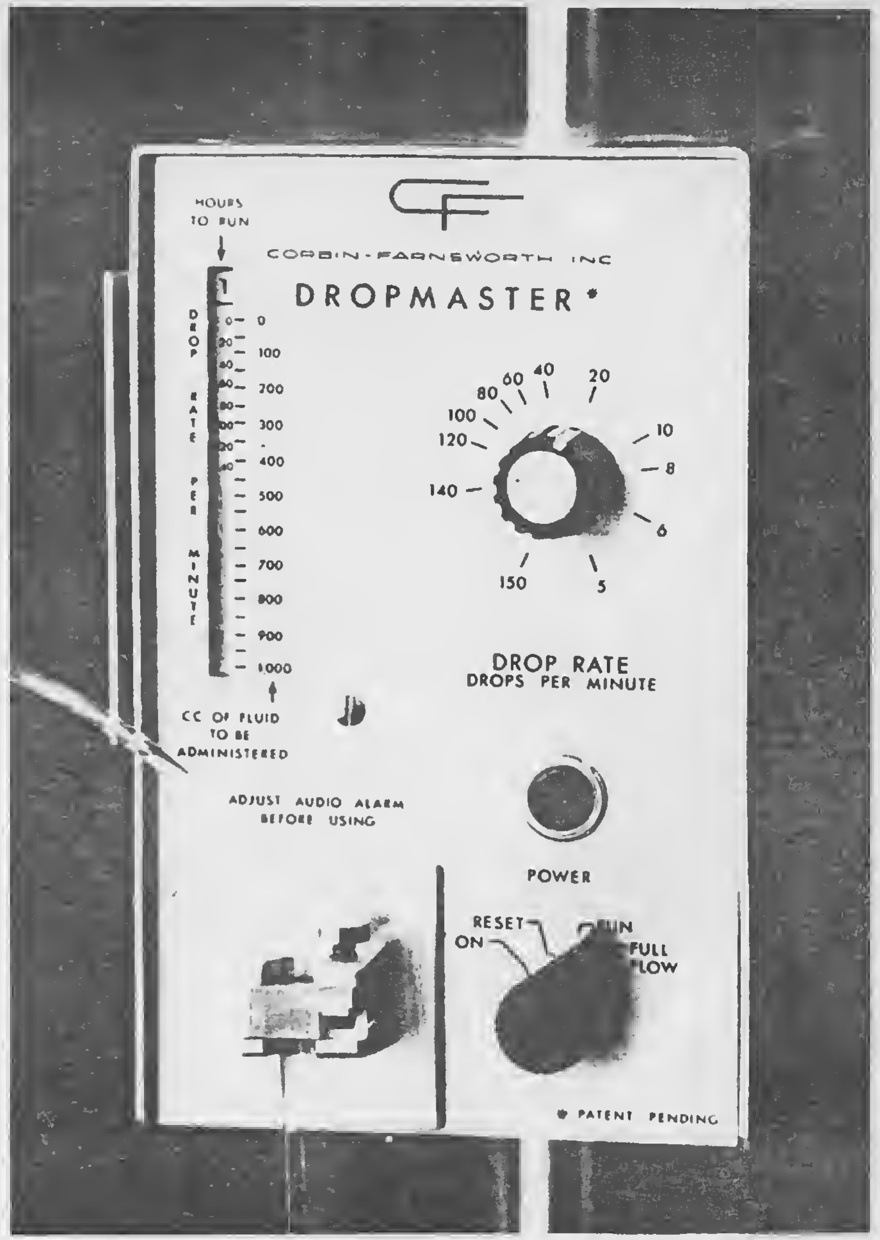


EXHIBIT A-2. Drop Master

May 24, 1966 T. H. CORBIN ETAL 3,252,623

APPARATUS FOR MONITORING DISPENSING OF LIQUID

Filed July 22, 1965 3 Sheets-Sheet 1

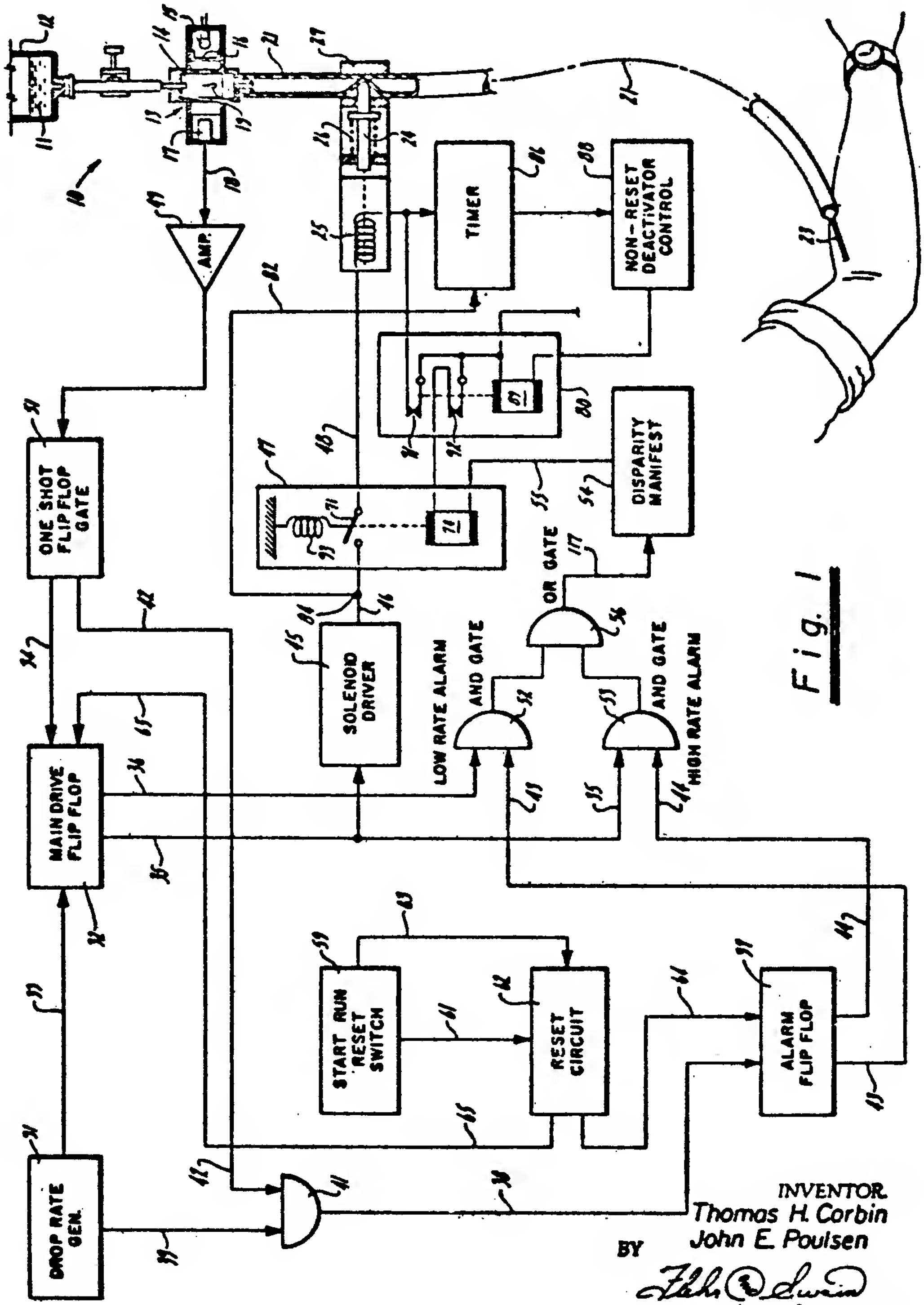


Fig. 1

INVENTOR
Thomas H. Corbin
John E. Poulsen

BY [signature]
Attorneys

May 24, 1966 T. H. CORBIN ETAL 3,252,623

APPARATUS FOR MONITORING DISPENSING OF LIQUID

Filed July 22, 1965 3 Sheets-Sheet 2

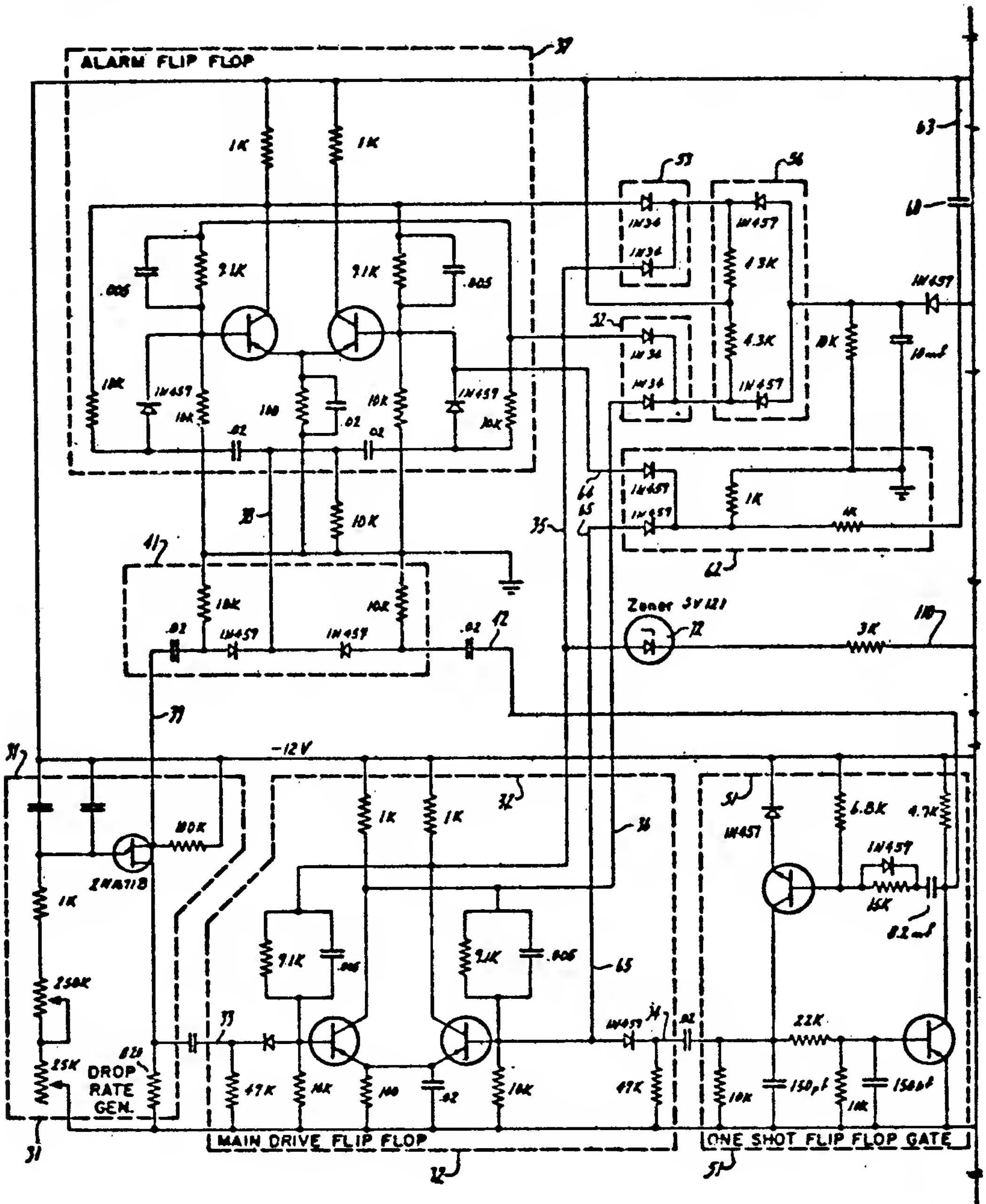


Fig. 2

INVENTOR
Thomas H. Corbin
John E. Poulsen
BY
Attorneys

May 24, 1966 T. H. CORBIN ETAL 3,252,623

APPARATUS FOR MONITORING DISPENSING OF LIQUID

Filed July 22, 1965 3 Sheets-Sheet 3

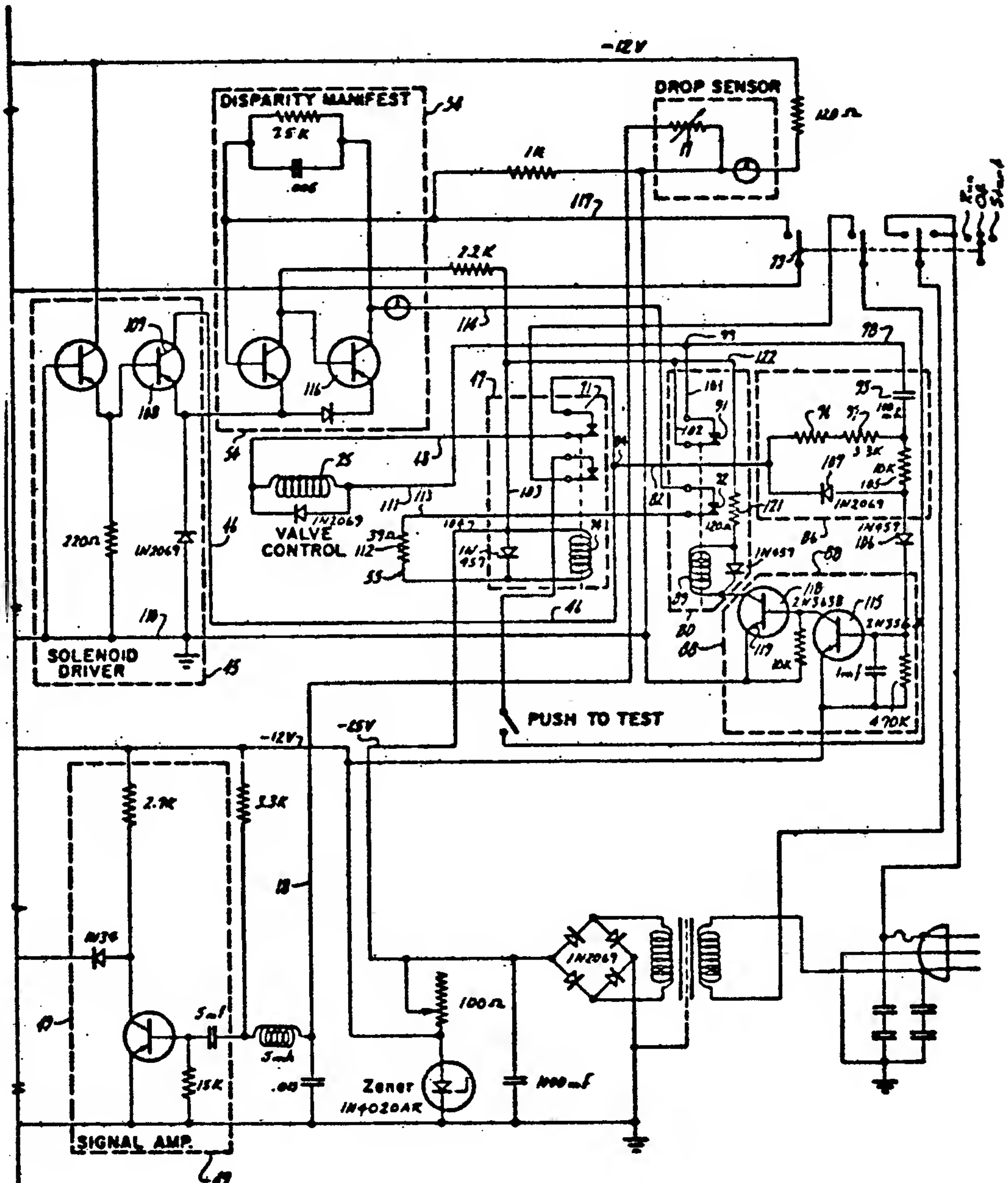


Fig. 3

INVENTOR
Thomas H. Corbin
John E. Poulsen
BY
[signature]
Attorneys

United States Patent Office

3,252,623

Patented May 24, 1966

1

3,252,623

APPARATUS FOR MONITORING DISPENSING OF LIQUID

Thomas H. Corbin, Palo Alto, and John E. Poulsen, Sunnyvale, Calif., assignors to C-F Liquidation Corporation, a corporation of California

Filed July 22, 1965, Ser. No. 474,076

7 Claims. (Cl. 222—59)

This invention is a continuation-in-part of our copending application Serial No. 362,832, filed April 27, 1964, now Patent No. 3,197,068 of July 27, 1965, and relates to apparatus for controlled feeding and monitoring of drops of liquid or other material delivered in discrete increments. The apparatus is particularly useful in maintaining a close watch over intravenous feeding of drops of liquid material to humans.

In feeding liquids intravenously to patients it is particularly important in certain circumstances to guard against feeding the patient at a faster rate than intended. In certain instances it is believed that more harm can be done the patient by feeding too rapidly than might be done, for example, in certain emergencies where all feeding might be terminated.

Systems of the kind described must safeguard the patient from the hazards of system failure or malfunctioning. It is a general object of the present invention to provide an improved scheme for monitoring the feeding of discrete increments of material wherein the hazards of equipment failure in the fluid feeding of a patient are minimized.

It is another object of the invention to provide a system for insuring against abnormally prolonged discrete deliveries of liquid as compared to a pre-determined safe duration thereof.

It is still another object of the invention to provide a drop feeding system which initiates and accurately controls the number of drops per minute of intravenous liquid delivered to a patient, and which turns itself off if the drop rate delivered to the patient is different from the drop rate desired or if the fluid delivery mechanism should remain activated unduly long.

It is yet another object to provide a system of the kind described whereby intravenous feeding of liquid is promptly terminated in case of various emergencies, such as power failure, etc., so as to be relatively "fail safe."

These and other objects of the invention will be more readily apparent from the following detailed description of a preferred embodiment when considered with the accompanying drawing in which,

FIGURE 1 is a schematic and block diagram of a material feeding and monitoring system according to the invention; and

FIGURES 2 and 3 considered together, provide a schematic circuit digram of an operating embodiment according to the invention, including values and specifications of circuit components thereof.

The system herein as described in detail further below pertains to apparatus for delivering a series of drops of liquid. Broadly, the system comprises means defining a selected drop rate and flow control means which provides delivery of the drops responsive to the selected drop rate. The flow control means is arranged to be operable between active and inactive states so as to respectively deliver or arrest liquid which is being delivered. In order to provide a virtually fail safe operation of the system and to safeguard against abnormal activation of the flow control means for unduly prolonged periods, the system herein further entails means for sensing initiation of the active state of the flow control means so that after a pre-determined period of elapsed time, the

2

flow control means shall be de-activated in a manner requiring manual re-setting of the circuit.

As will be apparent from the description below, the system includes means normally operative to de-activate the flow control means well before such time. In this manner, the system will normally operate the flow control means in a manner whereby it alternates between active and inactive states. Whenever it remains in its active state too long for safe operation it will be positively rendered inactive so as to safeguard against the hazards of remaining in its delivery condition too long.

Thus, in short, the fluid feeding means is operable between fluid delivering and fluid impeding conditions, under the control of an elapsed time detector which monitors the fluid delivering condition and compares the elapsed duration thereof with a pre-determined period considered safe.

The system as described generally above utilizes electromechanical valve means such as a solenoid controlled plunger arranged to be operable when energized so as to deliver a drop of liquid and when de-energized to arrest delivery. The means for normally alternately energizing and de-energizing the solenoid so as to deliver a series of drops at a selected drop rate wherein the solenoid remain normally energized for successive periods is preferably arranged as now to be described.

Generally, there is provided means defining a selected drop rate and means serving to sense each delivered drop so as to define the actual drop rate. Means are further provided which serve to detect disparity between the actual and selected rates and inactivate the valve means in response thereto in order to arrest further delivery of fluid.

More particularly a first pulse generator is arranged which serves to provide a series of pulses at a selected rate corresponding to the rate of delivery of drops of liquid intended to be achieved. A second pulse generator is arranged to sense each drop of liquid which is delivered. The second pulse generator serves to generate a pulse in response to sensing each drop.

A pair of bi-stable switch means such as conventional flip-flop devices are each coupled to respond to the pulses generated by both the first and second pulse generators. Each bi-stable switch means is, therefore, alternately driven between its two stable states by alternately receiving a pulse respectively from the first and the second pulse generators thereby maintaining an in-phase relationship. However, if this alternating application of pulses to both switching means is interrupted to cause successive application of pulses from either of the pulse generators to the two switching means this change is detected. Means are provided which serve to sense a change in the pre-determined phase relationship of the bi-stable devices and to condition the valve so as to terminate delivery of liquid. The existence of a change in the phase relationship of the operation of the two switching means is thereby registered.

Referring in detail to the schematic diagram shown in FIGURE 1 there is provided feeding means 10 servicing to feed a series of discrete drops of liquid 11 from a container 12 into the arm of a patient receiving intravenous feeding. Feeding means 10 as schematically shown includes a suitable drop forming outlet 14 disposed to deliver drops from container 12 to a splash chamber 13. An attachable drop sensor assembly includes a light source 15 which directs a beam of light through an aperture 16, and splash chamber 13, to be sensed by a photo responsive device 17. Device 17 serves to generate a signal on line 18 whenever the beam is interrupted by the presence of a drop as at 19. Drops 19 travel along a tube 21 for delivery into the arm of a patient.

Means are provided to control delivery of drops through tube 21. Thus, a valve member 24, operable in one condition to pass a drop of the liquid and operable in another condition to arrest delivery of drops through tube 21 is provided. A solenoid 25 is arranged whereby when it is energized member 24 will be withdrawn against the urging of spring 26. De-energizing solenoid 25 serves to permit spring 26 to cause member 24 to pinch tube 21. Tube 21 is pinched between the free end of member 24 and a fixed portion 27 of solenoid assembly.

From the foregoing it will be evident that the actual drop rate of liquid being dispensed is sensed by photocell 17. Photocell 17, therefore, serves to function as an impulse generator which provides an impulse corresponding to each drop to be dispensed.

There is also provided another impulse generator which serves to define the desired or selected drop rate for liquid to be fed to a particular patient. Thus, a drop rate generator 31 is provided in the form of a suitable pulse generator which provides a series of output pulses corresponding to the selected drop rate to be established. The frequency of these pulses can vary over a wide range, for example, from 5 to 150 drops per minute or the like and such a pulse generator can readily be provided by conventional means, such as by certain relaxation oscillators or the like.

In order to monitor and detect disparity between the actual drop rate and the desired drop rate there is provided a bistable switch means such as the "main drive" flip-flop 32. Flip-flop 32 is of conventional known design. Thus, it will be understood that flip-flop 32 includes a first input to be applied along line 33 to "set" the flip-flop and a second input to be applied on line 34 to "reset" the flip-flop. As known, a flip-flop has two stable states and these are indicated by the relative voltage level appearing on the two output channels 35, 36.

A second bi-stable switch means such as the alarm flip-flop 37 is arranged similarly to the "main drive" flip-flop 32 except that there is provided only a single input 38. Input 38 is arranged to receive the output pulses from drop rate generator 31 via line 39 and the OR gate 41 of conventional construction, which is arranged to pass a signal on either of two inputs 39, 42. Alarm flip-flop 37 having but a single input is a "complementary" flip-flop of conventional construction whereby each succeeding pulse received on input 38 serves to switch the state thereof from one stable condition to the other. The condition of flip-flop 37 is indicated by the voltage level or other suitable signal on each of two output channels 43, 44.

Means are provided whereby the drop rate generator 31, serves to dispense a drop of liquid to the patent. Thus, as a pulse appears at the output line 33 from drop rate generator 31, flip-flop 32 "sets" output channel 35 in its relatively high level potential. Channel 35, when "high," operates a solenoid driver circuit 45 which feeds a pulse on line 46 to energize solenoid 25 subject to control of an alarm disconnect relay circuit 37. When solenoid 25 is energized, member 24 is withdrawn permitting a drop to be dispensed.

The formation of a drop as sensed by photocell 17 provides a signal which is filtered and amplified by a conventional amplifier unit 49. This sensing signal serves to "reset" flip-flop 32 by developing a long pulse on input 34.

The signal from the photo-responsive device 17 is gated via a 150 millisecond monostable one-shot multivibrator 51 in order to prevent noise or extra signals from reaching flip-flop 32 and alarm flip-flop 37 for an elongated period, for example, on the order of 150 milliseconds after the drop occurs, thereby preventing false alarms. Multivibrator 51 can be of any suitable known construction whereby two operating states can be established. One state is a stable state while the other is unstable and after being established will revert, after a predetermined period to the stable state. The output of multivibrator 51 appears simultaneously on leads 34 and 42.

From the foregoing it will be readily apparent that a predetermined phase relationship is established between the bistable state of flip-flop 32 and the bi-stable state of alarm flip-flop 37, and that by alternately energizing solenoid 25, a series of drops will be dispensed.

In operation, as drop rate generator 31 provides an input pulse simultaneously to both flip-flops 32 and 37, one stable state of each will be established. At the same time a drop will be dispensed. Thereafter, formation of each drop will cause a pulse to be generated whereby flip flop 32 and flip-flop 37 change from their preceding state to their other stable state. So long as the pulse repetition frequency of drop rate generator 31 remains matched with the actual drop formation rate, flip-flop 32 will remain in its predetermined phase relation with respect to flip-flop 37.

However, means are provided to sense a change in the phase relationship and to cause the valve means to terminate the feeding of liquid.

Accordingly, a first and second AND gate have been provided, each being coupled to both flip-flops 32, 37. Flip-flop 32 and flip-flop 37 are each arranged whereby they can operate in-phase with each other. Thus, the high output from flip-flop 32 switches between lines 35 and 36 whereby it appears on line 35 at a time when line 43 is high and neither AND gate receives coincident application of the high states. On the other hand when line 36 is high from the "reset" pulse to flip-flop 32, line 44 will also be high.

The first and second AND gates are designated and shown as a low rate alarm AND gate 52 and as a high rate alarm AND gate 53. Gate 52 is fed by channels 36, 43. Gate 53 is fed by channels 35, 44. The AND gates 52, 53 are of a known style whereby coincident application of two relatively high voltage state signals is required to produce an output signal. It is to be noted that while flip-flops 32, 37 are operatively coupled so as to alternate in-phase between one stable state and the other they are coupled out of phase to AND gates 52, 53. Thus, normally only one high voltage state signal will be applied to each of the two AND gates 52, 53.

However, whenever both inputs to one or the other of the AND gates 52, 53 are high, then a disparity manifest circuit 54 receives a signal via OR gate 56 from one or the other of gates 52, 53 to provide a signal on line 55. This signal conditions (de-energizes) circuit 47 to prevent solenoid 25 from being energized and thereby precludes further delivery of liquid through tube 21. Circuit 54 comprises a flip-flop whereby manual open-circuiting of a control electrode thereof serves to reset the circuit as described below.

Thus, the high outputs from gates 52, 53 are fed to circuit 54 via a conventional OR gate 56 of the type adapted to pass either of two input signals. Assuming that the actual drop rate is low it will be evident that the drop rate generator 31 will provide two successive pulses on outputs 39 and 33 before an "actual" drop impulse is received by either flip-flop 32 or 37. The output of drop rate generator 31 on line 33 will be ineffective to switch flip-flop 32 inasmuch as the latter switches from one state to the other dependent upon the application of pulses alternately to the inputs 33, 34 respectively. On the other hand, flip-flop 37 has but a single input 38 and in response to two successive pulses will change its stable state whereby the high state signal on output channels 43, 44 will switch from one to the other. Thus, the high state signal of one flip-flop is switched whereas on the other, it is not. In this condition coincident existence of two high voltage signals will occur at AND gate 53.

If the actual drop rate is higher than the desired rate two successive impulses will appear on lines 34, 42 prior to generation of an impulse on lines 39, 33. Successive pulses applied to line 34, however, will not cause a trans-

fer of the high state from line 35 to line 36 for flip-flop 32, whereas successive pulses on line 42 will cause such a transfer from line 43 to 44. Thus, coincident existence of the high state signals will occur at AND gate 52. Accordingly, in either event circuit 54 is conditioned so as to deactivate the valve means and terminate delivery of liquid.

After arresting the feeding of liquid through tube 21, as caused by any rate disparity, the system is reset to re-establish a proper in-phase relation between flip-flops 32, 37 and to reset circuit 54.

Thus, the reset switch 59, when turned "off" operates a reset circuit 62 via lines 61, 63. Circuit 62 includes a pair of output leads 64, 65 coupled to respectively reset the alarm flip-flop 37 and the main drive flip-flop 32.

Having in mind the foregoing system operation which serves to alternately energize and de-energize the electromechanical fluid feeding means, the safety release portion of the system can be initially described briefly by reference to FIGURE 1 before proceeding with a more detailed description further below.

The safety release means which has been provided serves to sense unduly prolonged activation of the fluid delivery means whereby in response to such sensing the fluid delivery means is electrically de-coupled from the system. The de-coupling occurs at the solenoid 25 so as to insure against malfunctioning of the system which conceivably could retain solenoid 25 in its energized state. Thus, a safety release relay circuit 80 is coupled by a line 82 to a junction point 84 in line 46 so as to sense activation of driver circuit 45. So long as the driver circuit remains activated, an elapsed time detector or timer 85 continues to run. After a predetermined period of continuous energizaton of solenoid coil 25, timer 85 serves to operate a de-activator control circuit 88 which fires and energizes relay 89.

As now to be described, this action serves to de-energize the valve control solenoid 25. Thus, relay 89 controls contact points 91 and 92. As will be recalled, disparity manifest circuit 54 is arranged whereby relay 74 will ordinarily be energized so as to maintain the switch 71 closed until such time as any out-of-phase relationship appears. At such time as the selected drop rate and the actual drop rate show a disparity in their phase relation, relay 74 becomes de-energized to permit spring 93 to open line 46.

Switch 71 is also opened whenever relay 89 is energized since such action serves to open the contact points 92 through which relay 74 must be energized. Relay 89, when energized, also opens contact points 91 so as to de-energize solenoid 25 at a point immediately electrically adjacent same. While this action would normally be expected to de-activate solenoid 25, in the event that contact points 91 should happen somehow to become welded in closed position, the opening of contact points 92 would serve to disable relay 74 so as to insure de-activation of solenoid 25.

The elapsed time detector or timer 86, in general, includes a condenser 95 for gradually forming a predetermined control signal during energization of the solenoid 25. Condenser 95 is gradually charged via line 82 through a first circuit including resistances 96, 97, the other side of condenser 95 being connected to supply voltage via line 98, junction point 99, lead 101, contact points 91, and leads 102, 103, 104. Thus, the foregoing circuit serves to gradually charge condenser 95 immediately upon operation of solenoid driver 45, as will be described further below, so as to cause a comparison to be made between the elapsed period of solenoid energization and a predetermined period defined by the changing time of condenser 95.

A second circuit is provided which serves to remove the accumulated charge on condenser 95 at a time rate substantially greater than the time rate of forming the accumulated charge therein. Thus, resistance 105 and diode 107 are arranged in parallel with the circuit which included resistances 96, 97 whereby upon discharge of condenser 95 the parallel circuit so formed will quickly dissipate the accumulated charge and thereby "reset" the elapsed time generator circuit 86. Diode 107 is poled whereby during charging of condenser 95 the branch of the parallel circuit including resistance 105 is bypassed.

FIGURES 2 and 3 when taken together provide a preferred operable embodiment of the system when taken with the component values and designations shown on the drawing.

For ease in correlating the system taught in FIGURE 1 to the schematic circuit diagram of FIGURES 2 and 3 phantom lines have been used which somewhat generally enclose the elements thereof in the latter and have been given corresponding reference numerals.

Thus, the amplifier and filter circuit 49 is comprised of an RC coupled transistor fed from the photoresponsive device 17. The one-shot mono-stable multivibrator 51 includes a pair of transistors of opposite conductivity type wherein the emitter of one includes a pair of diodes poled in a common direction.

Main drive flip-flop 32 includes two transistors wherein the collector of one is fed back to the base electrode of the other. Separate input signals are received to "set" and "reset" the device as in the well known Eccles-Jordan trigger. Thus, flip-flop 32 is diode coupled to receive, and be "reset" by, pulses or step functions via line 34 defining the actual drop rate. Flip-flop 32 is "set" by pulses or step functions on line 33 which indicate the desired drop rate developed by pulse generator 31.

Pulse generator 31 includes a unijunction transistor wherein the control electrode is coupled to a junction between a series of three resistors and a relatively large capacitance formed by a pair of parallel condensers which serve to establish the pulse rate when the resistors are varied.

OR gate 41 includes a conventional arrangement of the two diodes shown wherein a signal on either line 39 or 42 will be fed out on line 38 from the junction between the diodes. The alarm flip-flop 37 is a conventional "complementary" flip-flop wherein a single input receives a succession of signals. Each signal received serves to switch the device from one stable state to the other. Thus, since signals are passed to flip-flop 37 via OR gate 41 from either the desired or actual pulse rate generator circuits without ability to distinguish one from the other, its state can be compared with the state of flip-flop 32 by means of AND gates 52, 53.

AND gates 52, 53 each include a pair of diodes arranged as is well known.

Relay driver circuit 54 includes a flip-flop circuit employing a pair of transistors. The output from circuit 54, when disparity in the phase relation between flip-flops 32 and 37 has been sensed, serves to de-energize a normally energized relay coil 74 in circuit 47. When the coil 74 is de-energized an armature 71 is spring-transferred by spring 93 to open-circuit the solenoid coil 25 of the valve operating solenoid.

Circuit 62 includes the two diodes poled in a normally non-conducting direction and passes a transient reset pulse from the condenser 60 upon initially plugging in the system to apply a reset function to the base (control) electrodes of one side of each flip-flop 32, 37.

Circuit 45 is Zener diode coupled by diode 72 to flip-flop 32 and includes a conventional two stage transistor amplifier circuit with the collector of the second stage directly coupled to solenoid coil 25 via leads 46, 48 and armature 71.

A manually operated switch 73, when positioned to the "off" position serves to de-energize the holding coil 74. Another position of switch 73 serves to permit pulse generator 31 to start dispensing drops while the system be-

comes adjusted, before implementing the drop arresting control portion of the circuit.

System operation of the safety release is as follows.

As noted above, condenser 95 is connected to supply voltage (—V) via line 98 and leads 101, contact points 91, and leads 102, 103, 104. When solenoid driver transistor 108 is driven into conduction its collector 109 will go virtually to ground on line 110. The lead 46 from its collector will accordingly be virtually at ground as will be junction point 84. The ground potential at junction point 84 serves to commence application of a charge to condenser 95 since the other side of condenser 95 is connected to ground. The ground potential of point 84 is further applied via the closed switch armature 71 of relay 74 which is then being held closed whereby supply voltage (—V) is applied across the coil of solenoid 25. The other side of coil 25 is connected to supply voltage (—V) via line 111 to junction point 99 and thence via leads 101, contact points 91, and leads 102, 103, 104.

As was mentioned switch relay armature 71 is held closed by the energized coil 74 operated by a circuit traced as follows. Lead 104 carries supply voltage (—V) to one side of coil 74. The other side of coil 74 is connected by a lead 55 through a resistance 112 and lead 113 to contact points 92 and thence by line 114 to its relay driver transistor 116. (It can be noted at this point that any disparity signal via line 117 is fed to the disparity manifest circuit 54 via manual switch armature 73 when positioned to its "run" position. Accordingly, the disparity signal on line 117 is connected so as to switch the disparity manifest circuit 54 off whereupon coil 74 would become de-energized.)

During the time that junction point 84 is held virtually at ground potential, condenser 95 will be charging. In the event that solenoid driver 45 is not turned off before condenser 95 acquires a predetermined charge then, in such event, as the charge on condenser 95 approaches the voltage on the emitter of transistor 115, transistor 115 will be switched on thereby switching on transistor 118.

When transistor 118 is driven into conduction, emitter 119 thereof will be carried substantially at ground potential via line 110. Accordingly, ground potential will be seen at one side of relay 89 whereas the other side of relay 89 will be carried at a potential between ground and supply (—V) via resistance 121 and lead 122. Therefore, when the control circuit 88 fires, relay 89 is energized and opens contact points 91, 92 thereby opening the circuit at a point electrically immediately adjacent the solenoid (contact points 91) and also disabling the disparity manifest output capability via line 55 (contact points 92).

It is to be appreciated that in the normal circumstance in the foregoing system, solenoid 25 will be de-energized prior to such time as condenser 95 acquires sufficient charge to fire circuit 88. In such event, condenser 95 is discharged quickly through the parallel circuit formed in one branch by resistances 96, 97 and in the other branch by resistance 105 and diode 107.

A circuit with the component values and voltages shown was constructed and operated.

Thus, there is provided an improved system for the controlled feeding and monitoring of drops of liquid. Drops are fed at a rate established by an impulse generator whereby an intended selected rate can be established. If the rate sought varies from the actual rate, the system manifests this disparity by a visual signal and shuts itself off. The system is relatively fail safe, since if power fails, the intravenous feeding tube will be immediately pinched closed. Furthermore, the voltage level sensing means provided by elapsed time generator circuit 86 is not responsive to electrical noise and other interference but serves to shut down feeding in the event that the fluid feeding line 21 remains open abnormally long.

We claim:

1. In apparatus for delivering a series of drops of liquid, means defining a selected drop rate, flow control means controlling delivery of the drops responsive to the first named means, the latter named means being operable between active and inactive states to respectively deliver or arrest liquid being delivered, means responsively coupled to sensed initiation of said active state for de-activating said flow control means after a predetermined period of elapsed time from said initiation, and means normally operative to de-activate said flow control means within said period, whereby the penultimate named means serves to safeguard against unduly prolonged activation of the flow control means in the event of malfunctioning by the last named means.

2. In apparatus for delivering a series of drops of liquid, electromechanical means operable when energized to deliver a drop of the liquid and operable when de-energized to arrest delivery of a drop of the liquid, means for normally alternately energizing and de-energizing said electromechanical means to deliver a series of drops at a selected rate wherein the electromechanical means remain normally energized for successive periods, and means responsive to energization of said electromechanical means for de-energizing said electromechanical means after a predetermined period of continuous energization thereof substantially exceeding the duration of the first named periods to safeguard against abnormally prolonged energization of said electromechanical means.

3. In apparatus for delivering a series of drops of liquid, electromechanical means operable when energized to deliver a drop of the liquid and operable when de-energized to arrest delivery of a drop of the liquid, means for normally alternately energizing and de-energizing said electromechanical means to deliver a series of drops at a selected rate wherein the electromechanical means remains normally energized for successive periods, and timer means for sensing initiation of energization of said electromechanical means and for gradually forming a control signal of predetermined duration, first electrically controlled switch means controlling said electromechanical means and normally energized to energize said electromechanical means, second electrically controlled switch means normally de-energized to both energize said electromechanical means and said first switch means, and de-activator means responsive to said timer means to receive said signal and energize said second switch means thereby de-energizing said electromechanical means.

4. Apparatus according to claim 3 wherein one of said switch means is disposed immediately electrically adjacent said electromechanical means.

5. In apparatus for delivering a series of drops of liquid, electromechanical means operable when energized to deliver a drop of the liquid and operable when de-energized to arrest delivery of a drop of the liquid, means for normally alternately energizing and de-energizing said electromechanical means to deliver a series of drops at a selected rate wherein the electromechanical means is normally energized for successive periods, and safety release means comprising first circuit means for gradually forming a predetermined control signal responsive to energization of said electromechanical means and second circuit means responsive to normal de-energization of said electromechanical means for removing said signal to await re-initiation thereof via said first circuit means, said second circuit means serving to remove said signal at a time rate substantially greater than the time rate forming said signal via said first circuit means, and means responsive to said signal to de-energize said electromechanical means thereby de-activating same.

6. In apparatus for delivering a series of drops of liquid, fluid feeding means operable between fluid delivering and fluid impeding conditions, elapsed time detector means operatively coupled to said feeding means to re-

spond to establishment of said delivering condition and initiate a predetermined period of time representing a maximum limit for the continuous establishment of said delivery condition, means operatively coupled to said fluid feeding means and said elapsed time detector means for comparing the elapsed duration of said fluid delivering condition with said predetermined period, and deactivating means operatively responsive to said comparing means to switch said feeding means to said fluid impeding condition whenever said elapsed duration equals said predetermined period.

7. Apparatus as defined in claim 6 further including means operatively responsive to said comparing means for resetting said elapsed time detector means upon establishment of said fluid impeding condition prior to expiration of said predetermined period.

References Cited by the Examiner

UNITED STATES PATENTS

2,672,581	3/1954	Gorham	222—55 X
2,882,937	4/1959	Kay	222—55 X
2,936,096	5/1960	Shawhan	222—76 X

RAPHAEL M. LUPO, *Primary Examiner.*

ENGINEERING CASE LIBRARY

ECL-150B

DROP MASTER (B)

Drop Master had been withdrawn from the market due to its over-sensitivity to temporary flow rate changes. Marty Kienitz was asked to look into the problem. Marty recalls: "Everybody was familiar with the Drop Master and how it worked. But when Tom asked for suggestions to improve the device, a solution was not immediately obvious." Realizing the importance of solving this problem, Marty got down to work.

 Prepared for the Stanford Engineering Case Program by Mr. R. Ganeriwal under the direction of Professor Henry O. Fuchs with financial support from the National Science Foundation. The assistance of Mr. Marty Kienitz and Mr. Paul Goldberg is gratefully acknowledged.

DROP MASTER (B)

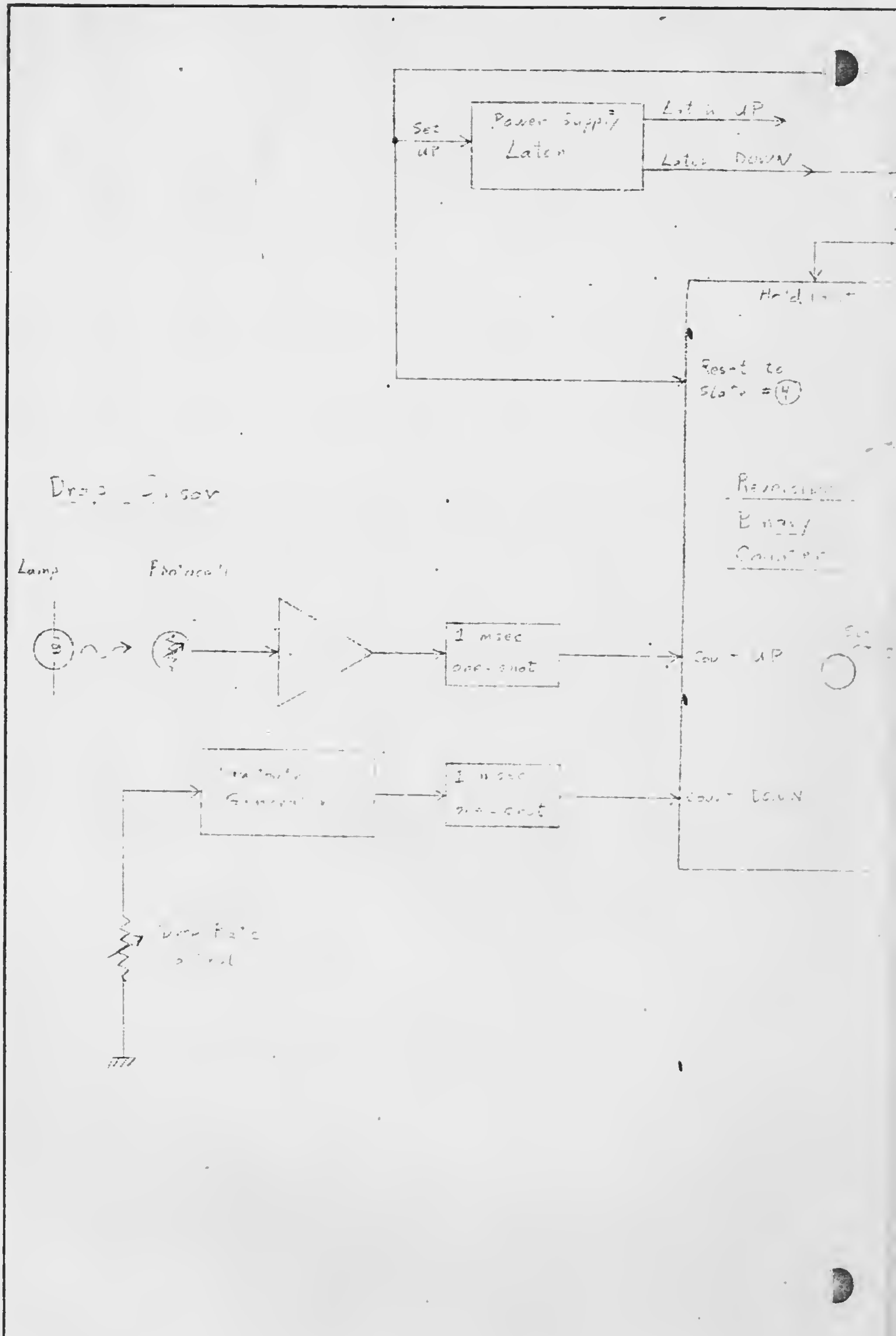
The objective was to make provisions for temporary departures from the set rate of flow without setting off the alarm. In the process of visualizing sequence of events in such a system, "I said to myself," explained Marty, "every time a drop is missed or an extra drop is received, instead of sounding the alarm, let us remember that this has happened."

That was it. The solution was straightforward from there on. The "Phase-Error-Feedback" system was conceived for improving the Drop Master; a drop master which would not only permit temporary change in drop rate but also compensate for the inconsistency in flow. The new Drop Master incorporating the "Phase-Error-Feedback" concept is designed to allow a discrepancy up to three drops before the system alarms. The "catching up" feature in this design provides, for example, three extra drops if three drops were missed. Similarly, the system detains the flow for the duration of three drops if the increased flow rate resulted in three extra drops over the set rate of flow. The alarm circuitry is activated if the discrepancy goes over three drops. In the following description of these design innovations, it will be shown that the allowable departure from the set rate of flow which can be built in the system can be varied by altering the number and arrangement of certain elements in the circuits.

The proposed new system is shown in block diagram form in Exhibit B-1. It is seen that the components of the system are:

1) a solenoid valve
2) a photoelectric drop sensor
3) an electronic "clock", or rate generator
4) a reversible binary counter output
5) digital logic to decode the binary counter output
6) several redundant safety circuits.

The first three of these are identical to the components of the original Drop Master. The last three are changed.



Set UP
Power Supply Latch
Latch DOWN
Reset to State #4
Lamp
1 msec
one-shot
Count DOWN

ECL 150B

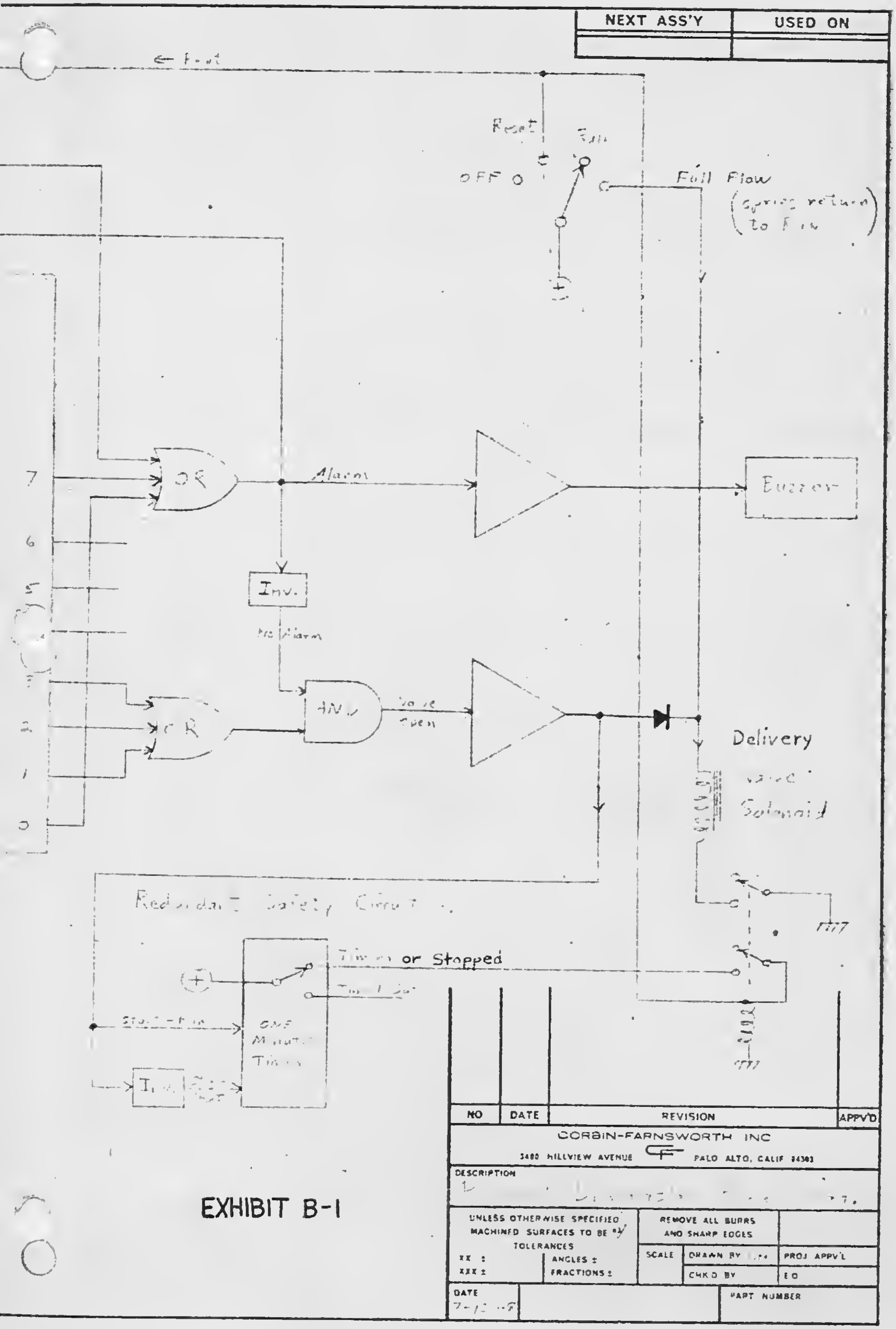


EXHIBIT B-1

The system operates in the following way: The reversible binary counter can be built up from three flip-flops and several gates, using standard electronic design techniques. It has eight possible output states, numbered zero through seven. There are four functional input lines: count-up, count-down, hold-count, and reset. A signal pulse applied to the count-down line will cause the counter to shift down one step to a lower numbered state. A similar pulse applied to the count-up line will cause the counter to shift up one step to a higher numbered state. A signal applied to the hold-count line prevents the counter from changing state even if pulses are applied to the count-up or count-down lines. A pulse applied to the reset line will cause the counter to assume state number four, which is called the starting state.

The output from the drop sensor is connected to the count-up line and the output of the rate generator is connected to the count-down line, so that pulses from these two sources cause the counter to be driven in opposite directions.

The outputs of counter states number one, two and three are connected through a conventional OR gate to the solenoid valve driver. The occurrence of any of these three states, and only these states, will cause the solenoid valve to be opened.

The outputs of the counter states number zero and seven are connected through a conventional OR gate to the alarm circuit. The occurrence of either of these two states, and no others, will cause an alarm. As before, a warning buzzer is sounded and power is disconnected from the solenoid valve so that it cannot open. In addition, the alarm activates the hold-count input of the counter, so that it remains in state zero or seven until an attendant resets it to the starting state by operating a front panel switch.

The outputs of counter states four, five, and six are not used. If any of these three states occur, the solenoid valve will not open, and the alarm will not be activated.

In normal operation the system is first reset to state four, the starting state, using the front panel switch. At the first pulse from the rate generator,

the counter drops to state number three and the solenoid valve opens. A drop forms and falls past the drop sensor, causing the counter to revert to state number four and the solenoid valve to close. As long as there is no interference to normal flow, the counter will oscillate back and forth between states three and four, and there will be one drop dispensed with each rate generator pulse.

If flow is impeded and no drops can form, the counter will continue to count down with each rate generator pulse, and the solenoid valve will remain open. If the obstruction is temporary, the drops will resume forming and falling in rapid succession, causing the counter to count up until it reaches state number four, whereupon the solenoid valve will close. In this way the number of drops will "catch up" with the number of rate generator pulses. If the obstruction is not removed, the counter will continue to count down with each rate generator pulse until it reaches state number zero, and the system alarms.

Conversely, if extra drops occur, the counter will continue to count up with each extra drop, but the solenoid valve will remain closed. If the more rapid flow is only temporary, then the rate generator will cause the counter to count back down to state number four when the number of rate generator pulses has "caught up" with the number of drops, and the solenoid valve is ready to open again. If the rapid flow does not stop, the counter will continue to count up until it reaches state number seven, and the system will alarm.

It is seen that the disparity between the actual number of drops and the number of rate generator pulses can be no greater than three without an alarm. It can also be seen that the system acts to equalize the number of drops and the rate generator pulses. In this manner the improved Drop Master can sense any disparity between the desired and the actual drop rate, compensate for any disparity that does occur, and alarm if the disparity becomes too large.

The digital control system here can be modified or extended in several ways that do not depart from the basic concept.

The number of flip-flops in the reversible binary counter can be increased or decreased thus, by changing the number of possible output states. The number of possible states of such a counter is given by:

$$\text{Number of states} = 2^N$$

where N is the number of flip-flops. If the highest and lowest numbered states are considered as alarm conditions, then the maximum possible disparity between drop pulses and rate generator pulses is:

$$\text{Maximum disparity} = 2^{(N-1)}$$

The reversible counter need not be restricted to a binary type, but may operate with any base, such as decimal. The binary counter is merely the simplest type to implement with state-of-the-art digital logic components.

The starting state need not be chosen half-way between the high and low alarm states, but may be put in the sequence. This would allow the system to have a larger permissible disparity in one direction than the other. For example, either two extra or three missing drops could cause an alarm.

The detailed circuit design in implementing these concepts was assigned to Paul Goldberg, an electronic engineer who works with Marty. There were no major problems encountered by Paul in working out the details. As Paul put it, "I was handed the logic diagram (Exhibit B-1). My assignment was to implement these ideas and <u>make it work</u>. The big problem was solved but there were <u>lots of little</u> things which had to be taken care of. But these are just run-of-the-mill everyday problems that you have to sit and figure out. Stuff in this device is nothing spectacularly new, just a combination of old ideas, which most engineering things are; combinations of things which already exist. You have an idea, then you take building blocks of things which are already in existence, like the binary counter, and put them together to accomplish your design."

Marty and Paul set up the new Drop Master for test. It now operates as intended.